

**REMARKS**

Applicant respectfully requests reconsideration of the current application.

Claims 33-56 are pending.

Claims 34, 35, 38, and 40-44 are amended. Support for these amendments appears in the following representative sections of the specification:

<b><u>Claims</u></b>	<b><u>Supporting Material</u></b>
Claim 34	Spec. at [0022] - [0024], [0027] - [0037], [143-0156], the section titled "Sequence Listing," and claim 36.
Claim 35	Spec. at [0022] - [0024], [0027] - [0037], [143-0156], the section titled "Sequence Listing," and claim 37.
Claim 38	Spec. at [0022] - [0024], [0027] - [0034], and claims 36, 49, and 50.
Claim 40	Spec. at [0022] - [0024], [0027] - [0034], and claim 36, 49, and 52.
Claim 41	Spec. at [0022] - [0024], [0027] - [0034], claim 49, and claim 53.
Claim 42	Spec. at [0022] - [0024], [0027] - [0034], claim 49, and claim 54.
Claim 43	Spec. at [0022] - [0024], [0027] - [0034], claim 49, and claim 55.
Claim 44	Spec. at [0022] - [0024], [0027] - [0034], claim 49, and claim 56.

Claims 33, 36, 37, 39, and 45 - 57 are canceled.

**Claim Objections:**

The Office objected to claims 33-56 and the specification for failing to adhere to the sequence rule requirements. (Office Action at 2.) Applicant amended the claims to include the appropriate sequence. In addition, Applicant respectfully notes that "SEQ ID NO: 2" as listed in the claims is identical to "SEQ ID NO 2" in the sequence listing. Thus, the current ground for objection may be withdrawn.

**Claim Rejections 35 U.S.C. § 112: Written Description**

The Office rejected claims 33-56 for failing to comply with the written description requirement. The Office stated that "the claims are drawn to a large number of peptides," "the current claims require that all peptides encompassed by the claims will elicit antibodies against CBD-1 peptide," and "the teachings of the art indicate that all currently claimed peptides will not effectively elicit antibodies with specificity to CBD-1 peptide." The Office further argues that "the claimed peptide structures lack the functional correlation" with the claimed invention. (See Office Action at 4.) According to the M.P.E.P., "[t]he first paragraph of 35 U.S.C. 112 requires that the 'specification shall contain a written description of the invention . . . .' This requirement is separate and distinct from the enablement requirement." See M.P.E.P. § 2163. In addition, "[t]he enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention." Moreover, "information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention." See

M.P.E.P. § 2164. Applicant respectfully submits that the quoted language from the Office Action constitutes an enablement rejection rather than a written description rejection and will address it later in this response.

Regarding the written description requirement, an applicant must use “such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.” M.P.E.P. § 2163.02. Applicant respectfully submits that the claims meet this test. The claims recite specific polypeptide sequences supported by corresponding disclosures in the claims. (See, e.g., Spec. at [0035] - [0037], [143-0156], and the section titled “Sequence Listing,” disclosing SEQ ID Nos: 2 and 4 appearing in claims 34 and 35 and imported by reference into the claims that depend therefrom.) Furthermore, Applicant amended claims 34 and 35 to recite specific amino acid sequences. Applicant also canceled claims 33, 36, 37, 39, and 45 - 57. Given that the claims recite peptides and that all of the sequences are described in the specification, the current application meets the written description requirements of 35 U.S.C. § 112.

**Claim Rejections 35 U.S.C. § 112: Enablement**

The Office also rejected claims 33-56 for failing to comply with the enablement requirement of 35 U.S.C. § 112. One basis for this rejection indicated that “the recitation of pharmaceutical composition in the claims implies that Applicant intends that the present composition will have a therapeutic effect when administered to humans.” (Emphasis in original.) (Office Action at 5-6.) Applicant has removed the disputed term from the claims. Applicant respectfully notes that the claims, however, still recite “or a

pharmaceutically acceptable vehicle,” which neither restricts nor requires use of the claimed composition as a pharmaceutical. As such, the claim conforms to the requirements of 35 U.S.C. § 112, first paragraph. Thus this rejection may be withdrawn.

The Office also appeared to indicate that the application does not enable the large number of peptides claimed. (Office Action at 5.) Applicant respectfully disagrees. The scope of the claims is supported by the specification. The claims recite defined peptide sequences, which have particular chemical properties. For example, claims 34-35, 38, and 40-44 recite peptides comprising either the sequence L-E-Q-I-W-N-N-M-T-W-M-Q-W-D-K (SEQ ID NO: 2) or C-T-T-A-V-P-W-N-A-S-W-S-N-K-S-L-E-Q-I-W-N-N-M-T-W-M-Q-W-D-K (SEQ ID NO: 4).

Moreover, as indicated by the Office, the examples in the specification show: (1) the CBD-1 peptide induces the generation of anti-CBD-1 antibodies in rabbits; (2) these anti-CBD-1 antibodies inhibited the HIV infection of T-Lymphocytes (MT4 lymphocytic cell line and primary PBMC derived CD4+ T lymphocytes) in vitro; and (3) immunization of macaques with peptides corresponding to SEQ ID Nos. 1-18 reduced SIV infection in vivo. (See Office Action at 5.) In addition, the specification indicates that Seq. ID NO: 4 possesses a significant degree of homology to CBD-1 (Spec. at [0129] - [0156]) and is also immunogenic (Spec. at [0242]-[0272]). The disclosed evidence, therefore, supports the conclusion that the sequence LEQIWNNMTWMQWDK and the chemical variant listed in SEQ ID NO: 4 exhibits the necessary immunogenicity recited in the claims.

Another ground indicated by the Office for the present rejection states that all currently claimed peptides will not effectively elicit antibodies with specificity to CBD-1

peptide. (Office Action at 4.) Without agreeing with the Office, Applicant amended claims 34 and 35 to remove the phrase "the immunogenic peptide immunologically reacts with antibodies raised against the CBD-1 peptide of sequence." Applicant also canceled claims 33, 36, 37, 39, and 45 - 57. Accordingly, the present claims are enabled by the specification as required under 35 U.S.C. first paragraph. Thus the pending claims 34, 35, 38, and 40-44 should be allowed.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 34, 35, 38, and 40-44 in condition for allowance. Applicant submits that the proposed amendments of claims 34, 35, 38, and 40-44 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.


In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art

references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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